03-080-1
442

Canadian Embassy

Ambassade du Canada

501 Pennsylvania Avenue, N.W.
Washington, D.C. 20001-2114

January 5, 2004

Regulatory Analysis and Development
PPD, APHIS, U.S. Department of Agriculture
Station 3C71
4700 River Road, Unit 118
Riverdale, MD 20737-1238
U.S.A.

RECEIVED

Attention: Docket No. 03-080-1
Subject: Comments on Proposed Rule "Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities", as published in the Federal Register of November 4, 2003.

We appreciate the opportunity to comment on the Proposed Rule "Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities", as published in the *Federal Register* of November 4, 2003. The Government of Canada, with the endorsement of the Canadian Provinces and Territories, wishes to submit specific comments for your consideration, as articulated in the attached paper.

The case of BSE diagnosed in Washington State and the international reaction, both in May of this year and under the current circumstances, underlines our mutual interest in cooperating to the maximum extent possible in the further development and implementation of measures to manage BSE risk within a North American context.

With this in mind, the essence of Canada's comments is that the definition of a BSE minimal risk region contained in the Proposed Rule has a strong foundation in science. Such an approach recognizes that public and animal health protection are integral to safe trade. Furthermore, in recognition of the mutual importance of integration to our markets, Canada's comments intend to identify measures to manage BSE risk in a way that is no more trade restrictive than necessary.

The United States and Canada strongly advocate the importance of basing public and animal health measures on scientific principles. Simply put, this is the most effective means of protecting our citizens and our resource base. Scientific principles also form a cornerstone of our respective policies regarding international trade rules and the relevant international standards with respect to the application of sanitary and phytosanitary measures. The United States Department of Agriculture (USDA) is to be applauded for the steps it has taken thus far in adhering to these principles in its response to the detection of BSE in Canada.

Furthermore, as two countries with a shared commitment to the protection of public health, food safety and animal health, we have made significant investments in these areas prior to the detection of BSE on the North American continent. Canada recognizes the advancements that the Proposed Rule provides in clearly establishing the importance of such investments as a basis for trade opportunities in animals and their products.

Prior to May 20, 2003, live cattle of all production classes, bison, sheep, goats, cervids, other ruminants, and camelids as well as products at all stages of production derived from these same animals, were relatively freely traded between Canada and the United States. Over the past five years 7.3 million head of live cattle alone have crossed the border in one direction or the other. Live cattle and these products also moved internationally as products originating from an integrated North American market. As you are aware, in response to the detection of BSE in Canada, many of our trading partners imposed temporary import bans on live ruminants and ruminant products from Canada pending the outcome of our investigation into the case. The United States import bans immediately cut off supply linkages for all live ruminants and ruminant products from Canada going beyond internationally-accepted measures under the World Organization for Animal Health (OIE), e.g. by banning ruminant hide derived products, ruminant semen and embryos.

Canada appreciates the assistance the USDA and other United States' agencies provided during the active investigation. Canada equally appreciates the United States' actions subsequently taken to re-establish certain ruminant-product trade with Canada. The import permit scheme for boneless beef and certain other low-risk products announced on August 8, 2003, and the Proposed Rule entitled "Bovine Spongiform Encephalopathy: Minimal Risk Regions and Importation of Commodities", are key steps on which we must continue to build in order to expeditiously reintegrate our markets based on measures commensurate with product risk.

In most respects, the Government of Canada finds the Proposed Rule to be consistent with the USDA and Harvard Risk Assessments. However, without compromising animal or public health objectives, it is our view that the same scientific risk analyses underpinning the Proposed Rule also support expanding the range of ruminants and ruminant-products eligible for import from Canada. These commodities include, for example, bovine products from animals over thirty months of age, where specified risk materials (SRM) have been removed; prepared products containing eligible ruminant meat; breeding stock of all species e.g., cattle, bison, sheep, goats, deer, elk, other live ruminants, llamas and alpacas born after Canada's feed ban was put in place as well as products derived from these same animals.

Finally, Canada recommends that USDA incorporate administrative flexibility into the Final Rule, understanding that such flexibility granted to the Administrator would be applied on the basis of an assessment of risk and sound science. Such an approach would provide for transparent and predictable application of the Rule, while accommodating advances in scientific knowledge and risk mitigation processes, and relevant revisions to the OIE standards or World Health Organization (WHO) guidelines.

The Government of Canada is committed to working in close collaboration with its United States counterparts to fully respect the public interest through the highest achievable inspection integrity and certification credibility both in North American management of BSE risk and in re-establishing, to the fullest level of integration possible, the North American market.

Canada proposes that these comments be considered as a basis for bilateral discussions, recognizing that products move both ways between the United States and Canada. Given the shared BSE risks and now equivalent management practices, we have a unique opportunity for our countries to clearly demonstrate international leadership in how BSE risk can be effectively managed in the least trade restrictive manner possible.

If you require any clarification, please contact either myself or John Masswohl at (202) 682-1755.

Yours sincerely,

Bertin Côté
Minister (Economic) and
Deputy Head of Mission

Enclosure

GOVERNMENT OF CANADA
Comments on Proposed Rule - Docket No. 03-080-1
"Bovine Spongiform Encephalopathy;
Minimal Risk Regions and Importation of Commodities"

This paper outlines specific comments that the Government of Canada wishes to submit for consideration by the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) in finalizing this Proposed Rule.

I. Risk factors for BSE Minimal-Risk Regions: Canada as a BSE Minimal-Risk Region

Canada supports the APHIS initiative to recognize an additional category of regions with regard to bovine spongiform encephalopathy (BSE) in the United States Code of Federal Regulations (CFR) referred to as the "*BSE minimal-risk region*". It is the Government of Canada's view that APHIS has identified appropriate factors for consideration and correctly proposes to apply them as a "*combined and integrated evaluation tool*" for scientifically evaluating the risk status of regions in order to qualify for this designation. Such an approach is consistent with the relevant international standards under the auspices of the World Organisation for Animal Health (OIE) and guidance from the World Health Organization (WHO). Moreover, the determination to designate Canada as a BSE minimal-risk region represents a well founded conclusion based on an objective assessment of the evidence.

II. Importation of Ruminant Commodities from a BSE Minimal-Risk Region: Canada

Building on the proposed framework for a BSE minimal-risk region, Canada considers the APHIS proposal to allow the importation into the United States of ruminant commodities from Canada that are identified in the Proposed Rule to constitute a very positive step in the direction of reintegrating the North American market on the basis of sound risk management principles.

The Government of Canada does not wish to unnecessarily encumber or otherwise delay the outcome of the rulemaking process for the classes of live animals and products that are specifically identified in the Proposed Rule. Having said that, Canada is of the opinion that the Harvard and USDA risk analyses underpinning the Proposed Rule, the relevant international BSE-related standards of the OIE, guidance of the World Health Organization and the policy announcements made on December 30 by USDA Secretary Veneman regarding additional mitigation activities in the United States, support the inclusion in the Final Rule of a number of additional low-risk animals and products.

As such, comments contained in this section are intended to identify ways in which the Final Rule can achieve the United States' intended outcomes, in terms of BSE-related human and animal health risk mitigation, in an effective and practical manner with respect to both (1) the animals and products identified under the Proposed Rule and (2) additional low-risk animals and products identified in Canada's comments.

A. Global Comments

A 1. Applying measures to the extent that is necessary

The Proposed Rule states *"the measures appropriate for specific commodities intended for importation would be determined by the presence or absence of factors that make it more or less likely the commodity might be contaminated or infected with BSE"*. Five factors are identified: feed source and exposure, animal age, tissue localisation, source species and prevalence of BSE. Each of these factors is then discussed in turn and measures are proposed for either live ruminants or ruminant products. Canada emphasises that it is important to consider that the impact of each measure on mitigating human and animal health risk is additive. The measure or combination of measures finally chosen should be no more restrictive than is necessary, that is, the measure(s) should be applied only to the extent that is necessary to effectively mitigate the health risks. The measure(s) should also be based on relevant international standards unless they are supported by a risk assessment that provides appropriate justification for adopting more restrictive approaches.

In this context, the Government of Canada would like to stress that, for Canada, the principal measure applicable to all commodities is that Canada is a minimal-risk region, that is, the likelihood of an animal or animal product *"introducing BSE into the U.S. via live ruminant and ruminant products is minimal"*. However, depending on the commodity under consideration, additional measures may be warranted; for example, commodities that are likely to be consumed by humans and/or animals. On the other hand, additional measures for commodities such as hard antlers used in art and craft production cannot be justified, as they would not be consumed by either humans or animals.

Recognizing that measures should only be applied to the extent that is necessary, the Government of Canada considers that, in addition to Canada being a minimal-risk region, two options are available to mitigate against the potential that a commodity might contain BSE infectivity. These options are supported by and consistent with the USDA's analysis and the supplementary information presented in the Proposed Rule. They are also consistent with relevant international standards in the OIE Code and WHO guidelines:

Either:

Option 1 – ensuring animals have not been exposed to BSE

Recognising the concern in the Proposed Rule that *"we cannot assume complete compliance with a ban on feeding of ruminant protein to ruminants"*, this option ensures that animals have not been exposed to BSE in Canada during their lifetime, by providing:

Certification by the Government of Canada that the animal was:

- born after the implementation of Canada's feed ban in 1997; and
- not known to have been fed ruminant proteins prohibited under Canada's feed ban during its lifetime.

Or

Option 2 – removing specified risk tissues from product

Recognising the observation in the Proposed Rule that "*the risks associated with tissue localisation can be mitigated by accepting only tissues that are unlikely to have infectious levels of the agent*", this option ensures that tissues that could potentially harbour infectivity are excluded (for a detailed discussion on the rationale supporting this option see section B 2.1 below) by providing:

Certification by the Government of Canada that those tissues in which infectivity has been demonstrated (referred to as specified risk material or SRM) have been effectively removed following slaughter, namely:

- the skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord, dorsal root ganglia of bovine animals aged 30 months or older; and
- the distal ileum in bovine animals of all ages.

With this in mind, the Government of Canada offers the following additional issue-specific comments, including recommendations as to which option would be applicable to the different commodities and types of products.

A 2. The nature and scope of the feed ban

In the Proposed Rule, the evaluation of Canada as a BSE Minimal Risk Region states that,

"Canada implemented a feed ban in 1997 that prohibits the feeding of most mammalian protein to ruminants. This ban exceeds what we consider the minimal necessary measure of banning the feeding of ruminant material to ruminants. Under the ban in Canada, mammalian protein may not be fed to ruminants, with certain exceptions. These exceptions include pure porcine or equine protein, blood, milk and gelatin. The feed ban is essentially the same as the feed ban in place in the U.S."

However, in the conditions for importation, the Proposed Rule would require veterinary certification for both live animals and animal products that the animals "*are not known to have been fed ruminant protein, other than milk protein, during their lifetime*". Since ruminant protein, other than milk, includes both blood and gelatin, this requirement is inconsistent with the statement referred to above that the feed ban in Canada "*exceeds what we consider the minimal necessary measure of banning the feeding of ruminant material to ruminants*". In addition, this requirement exceeds the relevant international standard outlined in the OIE Code, which requires that meat-and-bone meal and greaves derived from ruminants must not be fed to ruminants. As a result Canada asks for clarification as to whether APHIS intended to require veterinary certification of feed restrictions beyond those referenced in the section "Evaluating Canada as a BSE Minimal-Risk Region".

Canada recommends that the existing text in the Rule "*are not known to have been fed ruminant protein, other than milk protein, during their lifetime*" be replaced in all instances where it

appears with "*are not known to have been fed ruminant proteins prohibited under Canada's feed ban during their lifetime*"

A 3. Veterinary certification

If attestation of the scope and application by Canada of an appropriate feed ban is necessary, this could be accomplished more effectively through an exchange between Chief Veterinary Officers, rather than by veterinarians in the field.

Canada proposes that shipment-specific certification requirements should not include measures that were already considered by the United States in determining that Canada is a BSE minimal-risk region. Rather, they should be limited to the additional measures that are considered necessary such as verification of age in the case of live animals or removal of specified risk materials in the case of beef.

A 4. Method of permanent identification other than for immediate slaughter for imported live animals (ear tattoo)

The requirement that the inside of one ear on each animal (bovine, caprine and ovine) imported for feeding be, *"permanently and legibly tattooed with letters identifying the exporting country"* does not provide any degree of flexibility.

Canada proposes that the requirement be reworded as follows:

> "The inside of one ear on each animal is permanently and legibly tattooed with letters identifying the exporting country, or use of another means of identification deemed acceptable by the Administrator."

This would allow for the development of other acceptable animal identification and tracking systems and/or adoption of new technologies. This modification would assure the preservation of the identity of imported animals without limiting the ability of the Administrator to consider other reliable identification methods.

A 5. Ruminant animals of any class for temporary entry, e.g., livestock shows & rodeo, breeding or semen collection

Considering that the Proposed Rule recognizes Canada as a minimal-risk region with an effective feed ban in place since 1997 and that BSE is not transmitted horizontally, Canada proposes that the requirement for the temporary importation of animals into the United States be permanent identification as outlined in section A 4, and tracking in a manner that the Administrator deems to be appropriate to assure that the animals are returned to their country of origin.

A 6. United States origin bovines, sheep, goats, cervids, and camelids stranded in Canada following change in country BSE status from BSE free to minimal risk.

There are a number of ruminant animals, originally from the United States that have been effectively stranded in Canada following the closure of the United States' border in reaction to the discovery of BSE in Canada. To date, it has not been possible to enable the return of these animals to their owners in the United States. This issue is not addressed in the Proposed Rule.

Considering that the Proposed Rule recognizes Canada as a minimal-risk region, with an effective feed ban in place since 1997, Canada proposes that on confirmation that an animal is of United States origin, it be allowed to re-enter the United States with the following certification by the Government of Canada:

- the animal is not known to be have been fed ruminant proteins prohibited under Canada's feed ban during its stay in Canada.

A 7. Prepared products containing ingredients, including meat, derived from ruminants

Reference to processed and further processed products containing meat from ruminants is notably absent from the Proposed Rule. Canada assumes that this was an oversight because it would be illogical to permit the importation of ruminant meat in a fresh or frozen state and not permit the importation of the same meat because it had been further processed in some manner, e.g. ground, comminuted, seasoned, smoked, fermented, cooked, canned, etc. Because of the nature of BSE, and taking into account the measures under which fresh or frozen meat becomes eligible for importation into the United States, processing of the meat in a hygienic manner would not contribute to or increase the risk of BSE infectivity being in the product.

Therefore, Canada proposes that the Final Rule expressly permit the importation of prepared products containing ruminant meat, or an ingredient derived from ruminants that would be otherwise eligible for importation into the United States. This should include the wide range of further processed products that contain very small quantities of ingredients derived from ruminants for which access to the United States market remains difficult to non-existent under the current permit system. No further requirements should be necessary based on the rationale presented in following sections of these comments (e.g., Section B 2.)

In addition to Canada being a minimal-risk region, Canada proposes that for processed food products containing ingredients derived from ruminants, irrespective of quantity, the following measure would effectively mitigate potential BSE risk:

Certification by the Government of Canada that:

- the ruminant ingredients are limited to those eligible for export to the United States.

A 8. In-transit provisions for live animals and animal products

The Proposed Rule makes no mention of conditions under which live animals or products can transit the United States en route to Mexico or to a seaport for shipment to a third country. In

Canada's view, the conditions that are currently applied by the USDA are unnecessarily restrictive in relation to the requirement for transit permits to be issued to a United States resident or entity, and the refusal to allow trans-shipment of animals or products that do not meet BSE-related conditions for importation into the United States. Given the nature of BSE (e.g., not an infectious disease), Canada sees little risk being incurred by the United States from allowing trans-shipment of live animals and products that have been recognized as low-risk by another country and in accordance with the OIE Code. As a matter of course, the United States would want to ensure that the material being trans-shipped actually did leave the country as intended. This could be achieved by the application of existing Customs rules (e.g., shipment in bond) that are currently relied upon for other commodities and were previously relied upon for live ruminants and ruminant products.

B. Species-by-Species Comments: Importation of live ruminants and ruminant products

B 1. Bovine

The meaning of the term bovine in the Rule is unclear. In 9CFR93.400 (Definitions), while cattle are defined as *"animals of the bovine species"* the term bovine itself is not defined. As a result it is not clear whether bison and water buffalo are covered by the Proposed Rule. According to the Integrated Taxonomic Information System on the USDA's web site[1] the Subfamily Bovinae includes the Genus Bos, which includes cattle (*Bos taurus* and *Bos indicus*) and bison (*Bos bison*), and the Genus Bubalus commonly referred to as water buffalo (*Bubalus bubalis*). To ensure clarity, the Government of Canada proposes that the Final Rule include at least cattle, bison and water buffalo in the term bovine.

It is important to note that the Government of Canada's comments in this section apply equally to cattle, bison and water buffalo under the term bovine.

B 1.1 Live bovine animals, including cattle, bison and water buffalo

B 1.1.1 Live bovine animals less than 30 months of age for immediate slaughter or for movement to a feedlot and then to slaughter

Further to the points discussed earlier regarding Canada's feed ban, veterinary certification and animal identification, Canada proposes that, in addition to Canada being a minimal-risk region, the risk associated with BSE can be effectively managed by removing SRM at slaughter. In this circumstance, the additional measures in the Proposed Rule, that the animals are not known to have been fed ruminant proteins prohibited under Canada's feed ban, would not be necessary as the BSE risk is effectively mitigated by removal of the SRM. For this age group the appropriate SRM is the distal ileum.

---

[1] Integrated Taxonomic Information System. http://www.itis.usda.gov/servlet/SingleRpt/SingleRpt

Canada suggests that the requirement in the Proposed Rule regarding removal and disposal of "*the intestine*" is unnecessarily restrictive. As acknowledged in the Proposed Rule itself, the distal ileum is the only part of the intestine in which infectivity has been demonstrated. Therefore, Canada proposes that the appropriate reference in the Rule would be to specify the "distal ileum" rather than the whole intestine. This would not preclude USDA making a policy decision, as Canada has done with its own SRM removal policy detailed in a Meat Hygiene Directive[2] (see the discussion in B 2.1), to require removal of the entire small intestine until a practical and verifiable procedure is developed to ensure the removal of the distal ileum.

B 1.1.2 Live bovine animals other than those listed in B 1.1.1, including breeding stock

The Proposed Rule does not address breeding stock and other live bovine animals not included in the conditions for importing slaughter and feeder cattle under 30 months of age. In addition to Canada being a minimal-risk region, the following measures, which are consistent with the relevant international standard in the OIE Code, are proposed. It is important to note that once an animal reaches the end of its productive life in Canada and is sent to slaughter its SRM must be removed. This is an appropriate risk mitigation measure for BSE in Canada as there are no restrictions on the age of an animal or on its date of birth relative to the implementation of the feed ban as a precondition for eligibility for slaughter.

For bovine animals exported from Canada to countries where SRM are not removed at slaughter it is appropriate to ensure that a measure is applied that provides a corresponding level of assurance to that provided by removing SRM. In this case the appropriate measure is to ensure that the animal was not exposed to BSE during its lifetime by requiring that it was born after introduction of Canada's feed ban in 1997, was not fed prohibited ruminant protein during its lifetime and that it is permanently identified to allow trace back to its dam and herd of origin.

In this circumstance, Canada proposes that the appropriate import conditions for breeding stock and other live bovine animals not listed in section B 1.1.1 of these comments would be:

Certification by the Government of Canada that the animal:

- was born after the implementation of Canada's feed ban in 1997;
- was not known to have been fed ruminant proteins prohibited under Canada's feed ban during its lifetime; and
- is identified by a permanent identification system enabling it to be traced back to the dam and herd of origin and is not the progeny of a BSE suspect or confirmed female.

Secretary Veneman announced on December 30, 2003, that the United States will require meat establishments in the United States to remove, segregate, and dispose of SRM so that these tissues cannot enter the human food chain. This is consistent with actions already taken in Canada. Once this measure is implemented in the United States, the Government of Canada proposes that additional measures, over and above Canada being a minimal-risk country, will not

[2] Meat Hygiene Directive (2003-18), effective from July 24, 2003.
http://www.inspection.gc.ca/english/anima/meavia/mmopmmhv/direct/2003/direct18e.shtml

be required to effectively mitigate the BSE risk associated with the importation of live bovine animals of all ages from Canada.

B 2. Bovine products (including fresh (chilled or frozen) meat and offal, tallow, gelatin and blood products including serum and products derived from serum)

The Proposed Rule is essentially a general prohibition applied to meat and other products from bovine animals, with exceptions. As an alternative, the Government of Canada proposes that the Rule be structured to allow the importation of all meat and meat products, except those products that either are, include or are produced from, specified risk materials. The rationale supporting this recommendation and proposed measures to mitigate against the potential that a particular commodity might contain BSE infectivity are outlined in the following sections. Furthermore, we would note that such an approach would be compatible with the additional protection measures to guard against BSE that were announced by Secretary Veneman on December 30, 2003.

B 2.1 Fresh (chilled or frozen) meat including whole or half carcasses of bovines

Two of the proposed measures in the Rule, age and tissue localisation are interrelated and should not be considered in isolation. The Rule states that *"levels of infectious agent in certain tissues vary with the age of the animal"*, that *"the risks associated with tissue localization can be mitigated by accepting only tissues that are unlikely to have infectious levels of the agent or commodities derived from those organs or tissues"*, and that *"alternatively or in addition, if justified, risk materials can be removed"*. On the basis of these conclusions the Rule proposes to allow the importation of fresh (chilled or frozen) meat from bovines less than 30 months of age, provided their intestines are removed at slaughter. In this case, the distal ileum is the only risk material that might contain infectious levels of the agent should animals less than 30 months of age be infected. Similarly, the Rule proposes that tonsils be removed to mitigate the risk that tongues contain infectious material. Given this, it is not clear why meat derived from animals older than 30 months, where risk materials have been removed, is not also considered in the Rule.

In the Proposed Rule, risk materials are stated to be *"brain, tonsil, spinal cord, eyes, trigeminal ganglia, dorsal root ganglia and distal ileum"* and *"affiliated tissues or structures such as skull or vertebral column"*. These tissues, except for the vertebral column (see below), are collectively referred to as SRM in Canada in regulations under both the Food and Drugs Act[3] and the Health of Animals Act[4]. Consistent with risk analyses undertaken by the Harvard Centre for Risk

---

[3] Regulations amending the Food and Drug Regulations (1389 - Specified Risk Material), July 24, 2003. http://www.hc-sc.gc.ca/food-aliment/frila-raaii/food_drugs-aliments_drogues/part-partie_11/e_1389.html

[4] Regulations amending the Health of Animal Regulations (SOR/2003-264), August 13, 2003. http://www.inspection.gc.ca/english/reg/approe.shtml

Analysis[5] and the Government of Canada[6], together with scientific opinions from the European Commission, these tissues account for virtually all of the infectivity in a BSE-infected bovine.–

In July 2003, the Government of Canada issued a Meat Hygiene Directive[7] requiring removal of the distal ileum from cattle of all ages and all other SRM from cattle aged 30 months or older to prevent tissues that may contain BSE infectivity from entering the human food chain. While the vertebral column is not designated as a SRM in the Canadian legislation, the Meat Hygiene Directive requires that it be removed from cattle aged 30 months or older in order to ensure complete removal of the dorsal root ganglia. The Meat Hygiene Directive also prohibits harvesting of meat from the vertebral column of these cattle by mechanical means, including advanced meat recovery systems. In addition, the entire small intestine must be removed from cattle of all ages to ensure complete removal of the distal ileum. This latter policy will remain in effect until practical and verifiable procedures are developed to enable delineation and removal of only the distal ileum portion of the small intestine.

In the case of bison, establishments wishing to export bison meat to the United States are required to comply with the Meat Hygiene Directive on removal of SRM from cattle.

Considering that the Proposed Rule recognises Canada as a minimal-risk region with an effective feed ban in place since 1997, and that SRM are removed at slaughter, meat and meat products from bovine animals of all ages slaughtered and processed in Canada for export to the United States pose negligible risk of containing BSE infectivity. In these circumstances, the appropriate mitigation measure for fresh (chilled or frozen) meat, including whole or half carcasses of bovines, would be that the meat is derived from bovine animals slaughtered and processed in a facility approved and inspected by the Government of Canada. Since such a measure is consistent with the OIE recommendations for minimal-risk countries, it underpins United States leadership in the application of international standards to import measures commensurate with product risk.

Taking into account that SRM must be removed from bovines slaughtered in Canada, the Government of Canada recommends that, in addition to Canada being a minimal-risk region, the following measure would effectively mitigate the potential BSE risk associated with fresh (chilled or frozen) meat, including whole or half carcasses of bovines:

Certification by the Government of Canada that:

- fresh (chilled or frozen) meat, including whole or half carcasses of bovines, is derived from bovine animals slaughtered and processed in a facility approved and inspected by the Government of Canada.

---

[5] Cohen JT, Duggar K, Gray GM, Kreindel S, Abdelrahman H, HabteMariam T, Oryang D, Tameru B, 2001. Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States. United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Washington DC. http://www.aphis.usda.gov/lpa/issues/bse/bse-riskassmt.html

[6] Risk Assessment: Impact of SRM Policies on Potential Levels of BSE Infectivity in Food, July 2003

[7] Meat Hygiene Directive (2003-18), effective from July 24, 2003. http://www.inspection.gc.ca/english/anima/meavia/mmopmmhy/direct/2003/direct18e.shtml

B 2.2 Veterinary certification of compliance with a segregation process approved by the national veterinary authority of the region of origin and the Administrator to prevent contamination or commingling of the meat with products not eligible for importation into the U.S.

As outlined in the Proposed Rule, prior to the December 30, 2003 announcement by Secretary Veneman, were the United States to decide that it could demonstrably justify measures in excess of such a science-based international standard, Canada submits that it should at least acknowledge that meat and meat products derived from bovine animals aged 30 months or older from which SRM have been removed pose a very low risk of containing and transmitting BSE infectivity. This would be based on Canada being recognized as a minimal-risk country, the evidence that any prevalence of BSE in Canada would be very low, and the removal of infectivity localized in the SRM. With respect to prevalence, a risk assessment[4] conducted by Health Canada estimated that a prevalence of 1:1,000,000 would result in only one BSE-infected animal being presented for slaughter over a two year period. Using data from the EU Scientific Steering Committee, Health Canada has also estimated that removal of the tissues designated as SRM in Canada would eliminate more than 99% of the BSE infectivity that may be present in an infected animal.

Under these circumstances, there is no justification for extraordinary requirements for segregation of meat derived from animals under 30 months of age from meat derived from animals aged 30 months or older. In particular, the example of segregation provided in the "Supplementary Information" to the Proposed Rule which would entail "*slaughtering bovines over 30 months of age only at the end of the day on lines and with equipment dedicated exclusively to slaughtering such older animals*" would be extreme and not possible to achieve in existing slaughter facilities. Canada submits that the only segregation with any potential to have a meaningful effect on risk is already achieved in Canada by the current requirement for safe and effective removal of SRM on the kill floor and, in the case of dorsal root ganglia (vertebral column), in a cutting/deboning room. Once the SRM have been safely and effectively removed, risk from cross contamination and commingling would be negligible and easily controlled by good hygienic and manufacturing practices that are basic requirements in any sound meat inspection system, including Canada's.

Canada seeks confirmation that the role assigned to the Administrator in Section 94.19(b)(4) would be to approve a segregation process that had been approved by the CFIA as a standard for all slaughter facilities producing bovine meat for export to the United States, and not to approve the segregation process (i.e. segregation protocols or procedures) of each individual facility. The latter should clearly be the responsibility of the CFIA.

B 2.3 Fresh (chilled and frozen) bovine offal and other edible by-products

For offal, Canada proposes that the appropriate measures to mitigate against the risk that they might contain BSE infectivity is that, in addition to Canada being a minimal-risk region, the

offals do not contain the SRM specified in the Government of Canada's Meat Hygiene Directive[8] as identified in Section A.1.

It is important to note that the use of stunning methods that involve the use of air injection and/or pithing are prohibited in Canada.

Taking into account that SRM must be removed from bovines slaughtered in Canada, the government of Canada recommends that, in addition to Canada being a minimal-risk region, the following measure would effectively mitigate against the potential BSE risk associated with fresh (chilled or frozen) bovine offal and other edible by-products:

Certification by the Government of Canada that:

- fresh (chilled or frozen) offal and other edible by-products are derived from bovine animals slaughtered and processed in a facility approved and inspected by the Government of Canada.

B 2.4 Tallow

The measures in the Rule for tallow exceed the relevant international standard in the OIE Code. The Code defines tallow that contains a maximum of 0.15% impurities as protein-free tallow and states that, regardless of the BSE status of the exporting country there should be no restrictions on protein-free tallow. The Rule does not provide appropriate justification to support the following additional measures:

- derived from animals less than 30 months of age that were not known to have been fed ruminant protein other than from milk during their lifetime
- not derived from an animal that died otherwise than by slaughter
- the intestines were removed at slaughter

Canada proposes that the relevant international standards for tallow and tallow derivatives in the OIE Code be included in the Rule as they mitigate against any potential that such commodities might be contaminated with BSE. Specifically, it is proposed that for:

Protein-free tallow and derivatives made from this tallow

- Certification be provided by the Government of Canada that the tallow contains a maximum of 0.15% insoluble impurities by weight

Derivatives of non-protein-free tallow intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

[8] Meat Hygiene Directive (2003-18), effective from July 24, 2003.
http://www.inspection.gc.ca/english/anima/meavia/mmopmmhv/direct/2003/direct18e.shtml

- No measures required beyond Canada being a minimal-risk region

Non-protein-free tallow, that is tallow (other than protein-free tallow) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices should be allowed entry on the basis of:

In addition to Canada being a minimal-risk region, certification by the Government of Canada that the tallow:

- originates from bovine animals which have been subjected to an ante-mortem inspection for BSE with favourable results;
- has not been prepared using SRM
  - the distal ileum in bovine animals less than 30 months of age
  - the skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord, dorsal root ganglia, and distal ileum in bovine animals aged 30 months or older

B 2.5 Gelatin and collagen from bones

The measures in the Rule for gelatin from bones exceed the relevant international standard in the OIE Code. The Rule does not provide appropriate justification to support the following additional measures:

- it is derived from bovines less than 30 months of age when slaughtered that are not known to have been fed ruminant protein other than milk during their lifetime.

Since the OIE Code includes collagen derived from bones, the Government of Canada seeks clarification of whether and how the Rule would also apply to collagen.

Canada proposes that the relevant international standard for gelatin and collagen derived from bones in the OIE Code be included in the Rule as it mitigates against the probability that gelatin or collagen might be contaminated with BSE. This standard requires that if the bones come from a minimal-risk country they do not include skulls or vertebral columns from animals older than 30 months. As a result, Canada proposes that, in addition to Canada being a minimal-risk region:

Certification by the Government of Canada that the bones used in the production of gelatin or collagen intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices did not include the skull or vertebral column from bovines aged 30 months or older.

B 2.6 Gelatin and collagen prepared exclusively from hides and skins

In addition, Canada seeks confirmation that there will be no restrictions on gelatin or collagen derived exclusively from hides or skins. The relevant international standard in the OIE Code states that regardless of the BSE status of a country there should be no restrictions on gelatin or collagen prepared exclusively from bovine hides and skins. As a result, Canada proposes the following certification for gelatin or collagen prepared exclusively from hides or skins.

Certification by the Government of Canada that the gelatin or collagen was prepared exclusively from hides or skins

B 2.7 Blood products including serum and products derived from serum

Although BSE infectivity has not been detected in the blood of live cattle[9], contamination of blood might be theoretically possible either as a result of emboli containing central nervous tissue entering the bloodstream following slaughter with a penetrating device or from brain tissue leaking from the shot hole. The potential for such contamination is associated with the stunning method employed. It is important to note that stunning techniques that involve air injection and/or pithing result in significant brain damage and increase the potential for dissemination of brain tissue into the blood[10]. However, these techniques are prohibited in Canada.

As stated in the Rule, infectivity has not been detected in tissues apart from the distal ileum until at least 32 months post-exposure. As a result, the probability that blood collected from animals less than 30 months of age at slaughter might be contaminated with BSE would be negligible. In the case of animals older than 30 months, the potential that blood might be contaminated with BSE infectivity following stunning can be effectively mitigated by ensuring that blood is either collected from animals slaughtered with a non-penetrating stunning device or from live animals.

Considering that BSE infectivity has not been detected in tissues apart from the distal ileum until at least 32 months post-exposure, the probability that blood collected from a fetus, whose dam is less than 30 months old at the time of slaughter, would contain BSE infectivity is negligible. Following stunning, an animal is bled and skinned before the abdominal cavity is opened. Under the Government of Canada's Meat Hygiene Manual of Procedures[11], before fetal blood is collected, the uterus containing the fetus must be conveyed intact to a suitable room or area. These procedures would ensure that the potential that fetal blood might be contaminated with blood from its dam would be negligible.

In addition to Canada being a minimal-risk region, Canada proposes that, for blood products including serum and products derived from serum, the following measures would effectively mitigate against the likelihood that they would contain BSE infectivity:

Certification by the Government of Canada that the blood was collected:

- at the time of slaughter in a hygienic manner from either a fetus or an animal that is less than 30 months of age

or

---

[9] Update of the opinion on TSE infectivity distribution in ruminant tissues. November 2002.
http://www.europa.eu.int/comm/food/fs/sc/ssc/out296_en.pdf

[10] Scientific report on stunning methods and BSE risks (The risk of dissemination of brain particles into the blood and carcass when applying certain stunning methods). December 2001.
http://www.europa.eu.int/comm/food/fs/sc/ssc/out247_en.pdf

[11] Meat Hygiene Manual of Procedures, Chapter 6 – Inedible Meat Products
http://www.inspection.gc.ca/english/anima/meavia/mmopmmhv/chap6/6.1-6c.shtml

- from an animal older than 30 months of age which was either a live animal or was stunned with a non-penetrating stunning device.

B 3. Cervids (live animals, including deer, elk, caribou and reindeer, and their products)

The Government of Canada acknowledges that uncertainty remains regarding the susceptibility of cervids to the BSE agent although no cervids have to date been diagnosed with BSE, even in jurisdictions where a high prevalence of BSE has been recorded in bovines.

It should be noted that there are a number of programs in place for cervids in Canada designed to mitigate against risk of TSE exposure and to detect TSEs, including BSE, if it were to occur:

- Transportation Authorization Permits issued by CFIA are required prior to the movement of cervids from a farm for any reason;
- Mandatory reporting of all occurrences or suspected cases of TSEs with quarantine of suspected premises;
- Extensive surveillance and certification programs, appropriate for the region, for CWD and BSE, have been in place for several years and over 18,000 cervids have been tested to date, with no case of BSE found;
- All cervids are subject to the 1997 ban on feeding of ruminant protein;
- All cervid herds are tested for tuberculosis and examined for neurological symptoms every three years by CFIA veterinarians.

Canada considers that the potential BSE risks can be effectively managed by ensuring that the animals have not been exposed to BSE during their lifetime and seeks the introduction of appropriate conditions for market access accordingly. In addition to Canada being a minimal-risk region, Canada recommends that the following measures would effectively mitigate the potential BSE risks associated with:

B 3.1 Live farmed cervids for importation into the U.S. for breeding or hunt farms

Certification by the Government of Canada that the animal:

- was born after the implementation of Canada's feed ban in 1997;
- was not known to have been fed ruminant proteins prohibited under the feed ban during its lifetime;
- is identified by a permanent identification system enabling it to be traced back to the dam and herd of origin; and
- was a member of a herd participating in a TSE surveillance program and which is not known to have been infected with or exposed to a TSE.

B 3.2 Trophies from hunt farms

- Since these commodities would not be consumed by either animals or humans in the United States, they would not pose a risk. As such, specific mitigation measures over and above that of Canada as a minimal-risk region would not be necessary or appropriate.

B 3.3 Meat from Canadian hunt farms and farmed cervids

Certification by the Government of Canada that the animal:

- was born after the implementation of Canada's feed ban in 1997;
- was not known to have been fed ruminant proteins prohibited under Canada's feed ban during its lifetime; and
- was a member of a herd participating in a TSE surveillance program which is not known to have been infected with or exposed to a TSE.

B 3.4 Hard antlers from farmed or wild Cervids for use in arts and crafts

- This commodity is inedible and is used for art, craft and chandelier production. As such, specific mitigation measures over and above that of Canada as a minimal-risk region would not be necessary or appropriate.

B 3.5 Velvet antler and hard antler as natural health products

Since this is a consumable natural health product:

Certification by the Government of Canada that the animal from which the velvet or hard antler was harvested:

- was born after the implementation of Canada's feed ban in 1997;
- was not known to have been fed ruminant proteins prohibited under Canada's feed ban during it lifetime; and
- was a member of a herd participating in a TSE surveillance program and which is not known to have been infected with or exposed to a TSE.

B 3.6 Urine

Certification by the Government of Canada that the animal from which the urine was derived:

- was born after the implementation of Canada's feed ban in 1997;
- was not known to have been fed ruminant proteins prohibited under Canada's feed ban during it lifetime; and
- was a member of a herd participating in a TSE surveillance program and which is not known to have been infected with or exposed to a TSE.

B 4. Sheep and goats (live animals and their products)

BSE has never been diagnosed in either sheep or goats under natural conditions. It is known that certain genotypes of sheep have been experimentally infected with BSE and that the tissue distribution of BSE in these animals was widespread indicating that in this species, and perhaps in goats, SRM removal would not be as effective a measure for removing BSE infectivity compared to bovine animals. However, an alternative exists which would be to provide assurance that the animal was not exposed to BSE in the first place. In addition, this would make it unnecessary to maintain the 12 month maximum age restriction currently in the Proposed Rule.

In addition to Canada being a minimal-risk region, the following measures, based on ensuring that the animals have not been exposed to BSE during their lifetime, would effectively mitigate the potential BSE risks.

B 4.1 Animals destined for immediate slaughter or entry into a feedlot in the U.S. and for fresh meat from animals slaughtered in Canada

Certification by the Government of Canada that the animal:

- was born after the implementation of Canada's feed ban in 1997; and
- was not known to have been fed ruminant proteins prohibited under Canada's feed ban during its lifetime.

B 4.2 Live animals other than those covered in Section B 4.1 above

Certification by the Government of Canada that the animal:

- was born after the implementation of Canada's feed ban in 1997;
- was not known to have been fed ruminant proteins prohibited under Canada's feed ban during its lifetime; and
- is identified by a permanent identification system enabling it to be traced back to the dam and flock of origin

B 5. Camelids (live animals, including llamas and alpacas, and their products)

It is recognized that no targeted transmission studies have been undertaken and therefore uncertainty remains regarding the susceptibility of Camelids (alpacas and llamas) to BSE. Nevertheless, there has never been a recorded case of BSE or any other transmissible spongiform encephalopathy in camelids in any country. Futhermore, pathological examinations are carried out on the brains of llamas and alpacas on an annual basis in North America because of the presence of the common meningeal worm with no evidence of lesions compatible with a spongiform encephalopathy detected. Finally, it must also be recognized that the main use of camelids is not meat.

The Government of Canada proposes that, in addition to Canada being a minimal-risk region, the following measures, based on ensuring that the animals have not been exposed to BSE during their lifetime, effectively mitigate the potential BSE risks associated with Camelids:

Certification by the Government of Canada that the animal:

- was born after the implementation of Canada's feed ban in 1997;
- was not known to have been fed ruminant proteins prohibited under Canada's feed ban during its lifetime; and
- is identified by a permanent identification system enabling it to be traced back to the dam and herd of origin.

III. Administrative Flexibility

Canada notes that the Proposed Rule does not explicitly provide flexibility to accommodate evolution in the science of BSE and related risk mitigation alternatives, nor does it appear to provide scope to accommodate changes to the BSE Chapter of the OIE Terrestrial Animal Health Code. The Government of Canada urges the USDA to incorporate administrative flexibility into the Final Rule, understanding that such flexibility granted to the Administrator would be applied on the basis of an assessment of risk and sound science. Such an approach would provide for transparent and predictable application of the Rule while accommodating the evolution of scientific knowledge and risk mitigation processes, new product development, market demand and revisions to OIE standards or World Health Organization guidance.

In this context, the Government of Canada also requests confirmation that the authority granted to the APHIS Administrator under 9CFR Part 93 (93.401) under which the August 8, 2003 permitting scheme was created, remains applicable with the adoption and publication of the Final Rule.

IV. Other Considerations

Trade impact for countries that express BSE has changed since May 20, 2003

The negative trade scenarios outlined in the cost-benefit analysis of the Proposed Rule are based upon there continuing to be very few countries in the world that fully adopt or embrace the recommendations of the OIE as regards imports from BSE-affected countries. Such an underlying assumption is rapidly changing. As the Proposed Rule details, there are compelling reasons to conclude that the incidence of BSE in Canada is that of a minimal-risk country. In addition to the United States, an increasing number of Canada's other trading partners are acknowledging that Canadian imports can continue to be safely traded and are lifting the temporary import bans that were imposed on May 20, 2003 beyond what the Proposed Rule sets out. In addition, at the October 27-29, 2003 meeting of the World Trade Organization's Committee on Sanitary and Phytosanitary Measures, the OIE engaged to clarify the international obligations of importing and exporting countries with regard to BSE, and offered mediation assistance to facilitate the resumption of trade with countries affected by BSE.

The possibility that the United States would face lasting negative trade effects as a result of implementation of the Proposed Rule seems increasingly remote. Similarly, the statement that the detection of BSE in the United States would have negative economic consequences similar to the magnitude of those imposed on Canada would be mitigated by a positive science-based United States trade response to Canada, including the implementation of the Proposed Rule with the modifications proposed by Canada.

Government of Canada
January 5, 2004